

REMARKS

Claims 7-12 and 14-20 are all the claims pending in the application, prior to the present Amendment.

Claims 14-16, 23 and 26 have been rejected under the first paragraph of 35 U.S.C. § 112, as based on a non-enabling disclosure.

This rejection is based on the fact that a statement assuring irrevocable removal of restrictions on availability to the public for FERM BP-6898 has not been provided.

Applicants have canceled FERM BP-6898 from the claims. Accordingly, this rejection is moot.

Claims 7-12 and 14-26 have been rejected under the second paragraph of 35 U.S.C. § 112, as indefinite, as set forth at page 4 of the Office Action.

The Examiner states that the phrase “represented by the general formula” is indefinite because of the word “general.”

Although applicants disagree with this rejection, applicants have amended the claims to delete the word “general” from each place where it appears in the claims.

Claims 10, 12, 14-16, 23 and 26 have been rejected as indefinite because they recite the use of a “cultured product” or “processed product” of a recombinant microbe.

The Examiner states that it is unclear what are the metes and bounds of these recitations. The Examiner asks, for example, whether this phrase means the culture medium or an isolated enzyme from the microbe, or whether it includes some other meanings. The Examiner states that in the absence of a definition, it is unclear what these terms encompass.

With respect to the term “cultured product” of a recombinant microorganism, the present specification at page 17, defines a “cultured product of a microbe organism” as being a cultured solution containing microbial cells or cultured microbial cells. Applicants submit that in view of this definition, one of ordinary skill in the art would understand the meaning of the term “cultured product”. Further, the present specification refers to WO 98/35025 as disclosing culturing.

With respect to the term “process product” of a recombinant microbe, the present specification at page 17, states that “a processed product thereof” refers to, for example, a crude extraction solution, lyophilized microorganism cell, microorganism cell dried with acetone, and ground cells of microorganism. Thus, the cultured product is processed to form a crude extraction solution, lyophilized microorganism cell, microorganism cell dried with acetone or ground cells of microorganism.

Applicants submit that in view of the definition of the term “a process product thereof” as set forth in the specification, one of ordinary skill in the art would understand the meaning of this term.

In view of the above, applicants submit that the claims are not indefinite and, accordingly, request withdrawal of this rejection.

Claims 7-12 and 14-16 have been rejected as being incomplete because they do not recite a recovery step for the compound produced.

The Examiner states that while there is no specific rule or statutory requirement which specifically addresses the need for a recovery step and a process of preparing a composition, it is

clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. The Examiner states that the claims, therefore, fail to particularly point out and distinctly claim the complete process because the recovery step is missing from the claims.

Applicants disagree with this rejection.

Since the Examiner notes that a recovery step would be expected from conventional preparation processes, applicants submit that the claims do not have to recite such a conventional step. The purpose of the claims is to point out what is new, and not to recite conventional steps.

In view of the above, applicants submit that the claims are not incomplete and, accordingly, request withdrawal of this rejection.

The Examiner sets forth nine separate rejections of the claims over prior art, including newly cited prior art. Applicants discuss each of these rejections below.

Claims 7, 8 and 11 have been rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as obvious over U.S. Patent 4,734,367 to Leuenberger et al in view of the newly cited Barth et al article.

Applicants submit that Leuenberger et al and Barth et al do not disclose or render obvious the subject matter of claims 7, 8 and 11 and, accordingly, request withdrawal of this rejection.

Applicants have amended the present claims to delete all of the microorganisms that are disclosed in Leuenberger et al. Accordingly, Leuenberger et al do not disclose or render obvious the subject matter of the present claims.

The Examiner states that Leuenberger et al disclose that preferred microbes include those that belong to the genus *Candida*.

The Examiner further states that the newly cited Barth et al article discloses that a microbe belonging to the genus *Yarrowia* has also been classified as belonging to the genus *Candida* as set forth in the Abstract of Barth et al.

The Examiner argues, therefore, that use of microbes from the genus *Yarrowia* to effect biotransformation would be the same as, or closely related as being obvious from, the transformation by the microbes from the genus *Candida* which is disclosed in Leuenberger et al to produce predominantly either the (R) or the (S) isomer of the compound of formula (2).

Claim 7 recites the use of *Yarrowia* to produce the S configuration, and claim 11 recites the use of *Yarrowia lipolytica* to produce the S isomer.

Barth et al disclose that some of the yeast now belonging to *Yarrowia* had been previously classified as *Candida*. However, it is not a fact that all of *Candida* is now also classified as *Yarrowia*, and it is not a fact that all of *Candida* can catalyze the stereo-selective reduction of the presented invention.

Further, none of the yeast disclosed as *Candida* in Leuenberger et al has ever been classified into *Yarrowia*. Therefore, applicants submit that one of ordinary skill in the art would not expect that yeast belonging to *Yarrowia* can catalyze the stereo-selective reduction of the present invention.

In view of the above, applicants submit that Leuenberger et al and Barth et al do not disclose or render obvious the present invention and, accordingly, request withdrawal of this rejection.

Claims 7, 8 and 9 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative under 35 U.S.C. § 103(a) as obvious over Leuenberger et al in view of the newly cited ATCC Catalog.

The Examiner states that the ATCC Catalog indicates that microbes belonging to the genus *Nocardia* have been reclassified as belonging to the genus *Rhodococcus*.

The Examiner argues that since Leuenberger et al disclose employing microbes from the genus *Nocardia*, one of ordinary skill in the art would understand that microbes from the genus *Rhodococcus* could be employed in Leuenberger et al.

As discussed above, applicants have amended the present claims to delete all of the microorganisms that are disclosed in Leuenberger et al. Thus, applicants have amended claims 7 and 9 to delete *Rhodococcus* from claims 7 and 9.

In view of the above, applicants submit that Leuenberger et al and the ATCC Catalog do not disclose or render obvious the subject matter of claims 7 to 9 and, accordingly, request withdrawal of this rejection.

Claims 10, 14 and 16 have been rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over the newly cited JP 03-285689.

Claims 14 and 16 have been canceled, thus leaving claim 10 as the only claim that is subject to this rejection.

Claim 10 depends from claims 7 or 8. Since JP '689 has not been used against claims 7 or 8, it follows that JP '689 does not disclose or render obvious the subject matter of claims 7 or 8, or the subject matter of claim 10 which depends from claims 7 or 8.

JP '689 does not disclose or suggest a process that employs the microorganisms that are set forth in claim 10.

In view of the above, applicants submit that JP '689 does not disclose or render obvious the subject matter of claim 10 and, accordingly request withdrawal of this rejection.

Claims 7-9 and 11 have been rejected under 35 U.S.C. § 103(a) as obvious over Leuenberger et al.

Applicants submit that Leuenberger et al does not disclose or render obvious the subject matter of claims 7 to 9 and 11.

At page 12 of the Office Action, in the last paragraph under the heading "Response to Arguments," the Examiner refers to the *Rhodotorula* microorganism disclosed in Leuenberger et al.

As discussed above, applicants have amended the present claims to delete all of the microorganisms that are disclosed in Leuenberger et al. Thus, applicants have amended claims 7 and 9 to delete microorganisms belonging to the genus *Rhodococcus* and *Rhodotorula* from these claims.

With respect to *Yarrowia* recited in claims 7 and 11, as discussed above, none of the *Candida* yeast in Leuenberger et al has ever been classified into *Yarrowia*.

In view of the above, applicants submit that Leuenberger et al do not disclose or render obvious the subject matter of claims 7 to 9 and 11 and, accordingly, request withdrawal of this rejection.

Claims 17-22, 24 and 25 have been rejected under 35 U.S.C. § 103 (a) as obvious over Leuenberger et al in view of Kido et al.

The Examiner relies on Kido et al for disclosing the reaction of an acetic ester derivative (1) with a base and a formic ester to form (2), adding organic solvent and water to the reaction mixture and removing the aqueous layer containing (2). The Examiner particularly refers to page 5471 of Kido et al.

The Examiner argues that it would have been obvious to employ the technique of Kido et al in Leuenberger et al.

In response, as can be seen from the above amendments, the microorganisms that are disclosed in Leuenberger et al have been deleted from the present claims. Kido et al do not disclose the microorganisms that are set forth in the present claims.

In view of the above, applicants submit that Leuenberger et al and Kido et al do not disclose or render obvious the subject matter of the present claims and, accordingly, request withdrawal of this rejection.

The Examiner sets forth four rejections of the claims in which the Examiner relies on Leuenberger et al JP '689.

In the first rejection, claims 10, 14 and 16 have been rejected under 35 U.S.C. § 103(a) as obvious over Leuenberger et al in view of JP '689.

In the second rejection, claim 23 has been rejected under 35 U.S.C. § 103(a) as obvious over Leuenberger et al in view of JP '689 and further in view of Kido et al.

In the third rejection, claims 12, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as obvious over Leuenberger et al in view of JP '689.

In the fourth rejection, claim 26 has been rejected under 35 U.S.C. § 103(a) as obvious over Leuenberger et al in view of JP '689 and further in view of Kido et al.

Each of these four rejections is based on the Leuenberger et al patent as a primary reference. As discussed above, applicants have amended the claims to delete the microorganisms that are disclosed in Leuenberger et al.

In view of the above, applicants submit that Leuenberger et al and the secondary references do not defeat the patentability of the present claims and, accordingly, request withdrawal of these rejections.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
Application No.: 10/536,768

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Respectfully submitted,

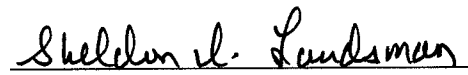
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